

**REMARKS**

According to the Office Action Summary, claims 1-17 are pending in this application and claims 9-17 are withdrawn. The Applicants respectfully submit that 24 claims were filed and are pending in this application. As such, the Applicants are assuming, for purposes of this amendment, that claims 1-24 are pending in this application and claims 9-24 are withdrawn.

The Applicants have amended claims 1, 2 and 8 and have canceled claims 12-24, without prejudice. The Applicants respectfully reserve the right to pursue the non-elected and/or canceled subject matter in a divisional application.

Upon entry of the present amendment, claims 1-8 are pending in this application, claims 9-11 are withdrawn and claims 12-24 are canceled.

**I. Election/Restrictions**

Restriction to one of the following inventions was required under 35 U.S.C. §121:

- I. Claims 1-8, drawn to compounds, simple compositions where  $Y=N$ , classified in class 544, subclasses 361, 363 and many other subclasses based on nature or Ar and Q ring; class 514 subclasses 253.03, 253.07, etc.
- II. Claims 1 and 8, drawn to compounds, simple compositions where  $Y=CH$ , classified in class 546, subclasses 157-158 and class 544 various subclasses based on Ar and Q ring; class 514 subclass 312, etc.
- III. Claims 9-15, drawn to multiple uses employing compounds of I, classified in class 514, subclass 253.03, etc.
- IV. Claims 9-15, drawn to multiple uses employing compounds of II, classified in class 514, subclass 312, etc.
- V. Claims 16-17, drawn to multiple uses employing compounds of I and additional active ingredients, classified in class 514, subclasses various as determined by the exact nature of ingredients employed.

- VI. Claims 16-17, drawn to multiple uses employing compounds of II and additional active ingredients, classified in class 514, subclasses various as determined by the exact nature of ingredients employed.

The Applicants hereby elect Group I for prosecution on the merits without traverse. As such, Applicants hereby have amended claim 1, withdrawn claims 9-11, and canceled from prosecution, claims 12-24, directed to the non-elected subject matter, without prejudice. The Applicants respectfully reserve the right to file a Divisional application(s) to the non-elected subject matter.

Applicants were also required to elect a single species embrative of the elected group. Applicants hereby elect the compound of Example 3, 8-[2-(4-1,2-benzisothiazol-3-yl-piperazin-1-yl)-ethyl]-6-fluoro-4,4-dimethyl-3,4-dihydro-1H-quinolin-2-one, for prosecution.

## **II. Objection to the Disclosure**

The Office has objected to the disclosure because the parent history is missing, which identifies the earlier provisional application.

The Applicants respectfully submit that a Preliminary Amendment, which included the priority claim to the earlier provisional application, was filed on September 26, 2003 with the filing under 37 CFR 1.53(b) of the present application. For the convenience of the Office, the Applicants have provided the priority claim in the section above entitled "Amendments to the Specification."

If the Applicants have misunderstood the grounds of the objection, the Applicants respectfully request clarification of same.

**III. Rejections under 35 U.S.C. 112, second paragraph**

The Office has rejected claims 1, 2, 4, 5, 7 and 8 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention.

Specifically, the Office states that “preferably” in the definitions of “Ar”, “Q”, “R<sup>1</sup>” and “R<sup>5</sup>-R<sup>8</sup>” in claim 1 renders the scope indefinite since it is not clear what is being claimed, the subject matter before or after the term. In response, the Applicants have amended the definitions of “Ar”, “Q”, “R<sup>1</sup>” and “R<sup>5</sup>-R<sup>8</sup>” in claims 1 and 2.

The Office also states that “oxo” as a substituent on heteroaryl moieties would exceed the valency requirements in such ring systems. In response, the Applicants have amended claim 1.

Finally, the Office states that the plethora of intended uses present in the composition claim 8 renders the intended “amount” ambiguous. In response and as per the recommendation of the Examiner, the Applicants have deleted the uses from claim 8.

Based on the foregoing, the Applicants respectfully submit that the rejection of claims 1, 2, 4, 5, 7 and 8 under 35 U.S.C. 112, second paragraph, has been overcome and respectfully request that the rejection be withdrawn.

**IV. Rejections under 35 U.S.C. 112, first paragraph**

The Office has rejected claims 1, 2, 4, 5, 7 and 8 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The Office states that the claim(s) contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention.

Specifically, the Office states that the starting material sources for the polycyclic rings resulting from one of  $R^5$  to  $R^8$  joining with another  $R^5$  to  $R^8$  and spiro fusion at these variables, as well as in Q, are not seen but are required. The Office acknowledges that the Applicants have exemplified polycyclo ring systems, such as those corresponding to ortho fusion resulting in a cyclopentane ring (Example 32) and peri fusion resulting in a benzene ring (Example 36); however, the Office also states that since there are no other such polycyclic compounds that have been made corresponding to the instant scope which includes carbo- and heterofused rings having 3 to 7 members and all degrees of unsaturation, that there is no reasonable basis for assuming that all of the compounds embraced by the generic claims will all share the same physiological properties since they are so structurally dissimilar as to be chemically non-equivalent and there is no basis in the prior art for assuming the same. The Office applies the same argument for the scope of substituents permitted on the Q ring system, which includes heteroaryls which can be monocyclic, bicyclic and further substituted with more groups.

To expedite the prosecution of this application, the Applicants have amended claims 1 and 2 to delete the subject matter related to polycyclic rings resulting from one of  $R^5$  to  $R^8$  joining with another  $R^5$  to  $R^8$  and spiro fusion at these variables, as well as the spiro fusion at Q. The Applicants have also deleted certain of the substituents permitted on the Q ring system, such as heteroaryls and substitutions thereof, from claims 1 and 2.

Based on the foregoing, the Applicants respectfully submit that the rejection of claims 1, 2, 4, 5, 7 and 8 under 35 U.S.C. 112, first paragraph, has been overcome and respectfully request that the rejection be withdrawn.

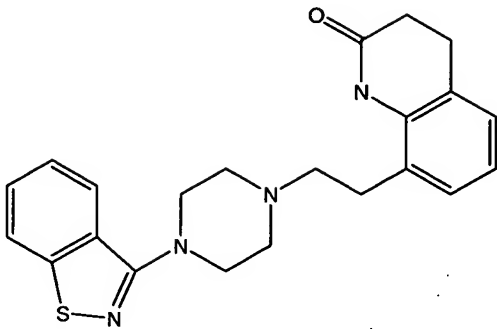
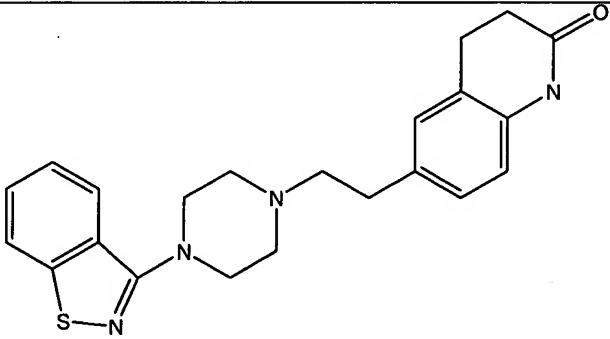
#### **V. Rejections under 35 U.S.C. 103**

The Office has rejected claims 1-8 under 35 U.S.C. 103 as being unpatentable over Howard (EP '435). The Office states that Howard describes very similar compounds to that claimed in the present invention for use in treating psychosis and anxiety. Said compounds differ from that claimed in the present invention only in point of attachment to the quinolinone

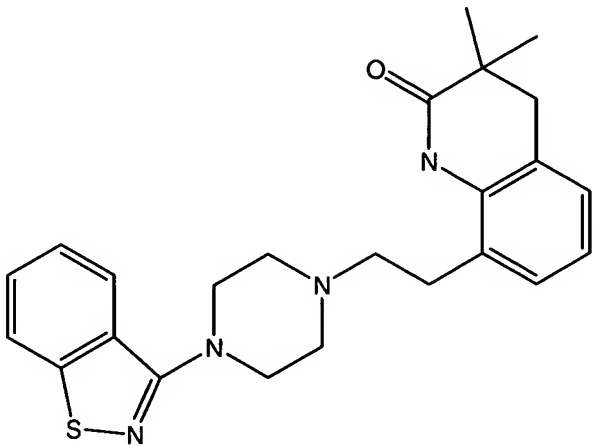
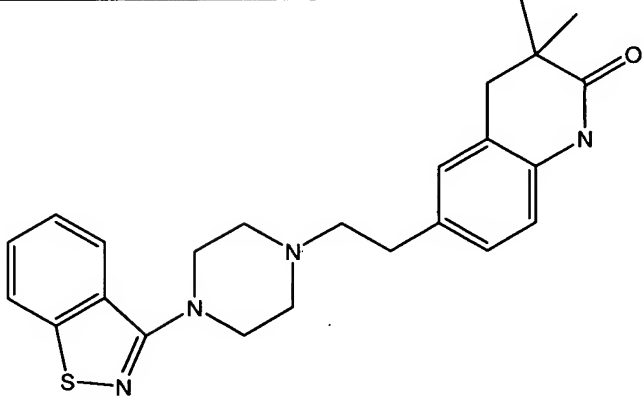
ring system; i.e., at the 6-position in Howard vs. the 8-position in the present invention. The Office concludes that it would have been obvious at the time the invention was made to expect instant compound to possess the utility taught by the applied art in view of the close structural similarity.

In response, the Applicants respectfully submit that it would not be obvious to one of ordinary skill in the art that compounds of differing spatial orientation would provide a similar profile/activity to possess the utility taught by Howard. It would not be obvious that a change in the spatial orientation of a ring system would result in a similar profile/activity.

For example, as shown below, when three-dimensional depictions of compound A (Example 4 of this invention, PC25413) and compound C (Example 37 of Howard) are overlapped, the alignment of the bulk of the molecule is similar, but there are obviously different orientations of the red oxygen atoms.

Compound	Reference	Example No.	Structure
A	Present invention (PC25413)	4	
C	Howard	37	

Additionally, as shown below, when three-dimensional depictions of compound B (Example 44 of this invention, PC25413) and compound D (Example 44 of Howard) are overlapped, the alignment of the bulk of the molecule is similar, but there are obviously different orientations of the red oxygen atoms.

Compound	Reference	Example No.	Structure
B	Present invention (PC25413)	44	
D	Howard	44	

Based on the foregoing, the Applicants respectfully submit that the rejection of claims 1-8 under 35 U.S.C. 103 has been overcome and respectfully request that the rejection be withdrawn.

**VI. Provisional Rejection under Obviousness-type double patenting**

The Office has stated that claims 1-8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application Serial No. 10/660,908.

The Applicants hereby state that the instant application and copending were commonly owned at the time the instant invention was made.

The Applicants hereby acknowledge the provisional rejection under the judicially created doctrine of obviousness-type double patenting. No terminal disclaimer will be filed at this time.



**VII. Conclusion**

Upon entry of the present amendments, the Applicants submit that this application is now in condition for allowance, which allowance is respectfully solicited.

If the Examiner believes that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at 734-622-2658.

Respectfully submitted,

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